

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Silke KOHLHASE et al.

Confirmation No. 6657

Group Art Unit: 1617

Serial No. : 10/759,160

Examiner: Jean-Louis, Samira

Filed : January 20, 2004

For : PEARLESCENT COSMETIC OR DERMATOLOGICAL FORMULATIONS

REPLY BRIEF UNDER 37 C.F.R. § 41.41(a)(1)

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Appeal Brief - Patents
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This Reply Brief is in response to the Examiner's Answer mailed January 8, 2009, the period for reply extending until March 9, 2009 (March 8, 2009 being a Sunday).

In the Examiner's Answer all grounds of rejection set forth in the final rejection are maintained.

Appellants note that the Examiner's Answer does not sufficiently address several of Appellants' arguments as to why the rejections are without merit, and misrepresents some of the facts. These deficiencies have prompted the present Reply Brief.

Appellants also note that this Reply Brief is being filed under 37 C.F.R. § 41.41(a)(1) and is directed to the arguments presented in the Examiner's Answer, and therefore must be entered unless the final rejection is withdrawn in response to the instant Reply Brief.

In order to avoid repetition, the following response to the Examiner's arguments in the Examiner's Answer will be limited to issues which are important enough to warrant a further comment in Appellants' opinion. Accordingly, Appellants' silence with respect to any

allegations set forth in the Examiner's Answer which are not specifically addressed below should by no means be construed as Appellants' admission that these allegations are of any merit.

REPLY

1. It is noted that with respect to Appellants' argument that due to the fundamental differences between the biocompatible cosmetic or dermatological oil-in-water emulsions for skin care taught by Riedel et al., U.S. Patent No. 6,558,680 (hereafter "RIEDEL") and the skin wash compositions for topical application to water-wetted skin taught by Charlton et al., U.S. Patent No. 6,486,106 (hereafter "CHARLTON") there is no apparent reason for one of ordinary skill in the art to combine the teachings of RIEDEL and CHARLTON, "the Examiner contends that one of ordinary skill in the art would have the motivation to add any component of [CHARLTON] into the composition of [RIEDEL] since both compositions are comparable and used for the same purpose". Page 10, end of first paragraph of Examiner's Answer.

Appellants again respectfully disagree with the Examiner in this regard. In particular, it is not seen that an oil-in-water emulsion according to RIEDEL which is intended for skin care and accordingly is provided in the form of, for example, a skin protection cream, a skin lotion, a cosmetic milk, a sun protection cream, a sun protection milk, a cleansing milk, a sunscreen lotion, a nourishing cream, a day or night cream, etc. (see, e.g., col. 9, lines 39-43 and paragraph bridging columns 9 and 10 of RIEDEL) is comparable to, and used for the same purpose as the skin wash composition of CHARLTON which is applied to water-wetted skin and subsequently rinsed off and comprises an alpha-hydroxy acid active ingredient formulated in a mild and non-irritant

detergent base and does not appear to contain any oils (lipids). In view thereof, Appellants submit that the Examiner's analysis of obviousness based on a combination of RIEDEL and CHARLTON is without merit for this reason alone.

2. Appellants note that in the paragraph bridging pages 11 and 12 of the Examiner's Answer it is alleged, *inter alia*, that "applicant's own specification teaches that emulsions from the prior art have a pearlescent effect due to the presence of mono and di-fatty ester of glycerol or glycol ... and sodium and potassium hydroxide ...; all of which are taught as ingredients in the compositions of [RIEDEL]. Moreover, the Examiner contends that addition of pearlescent pigments such as titanium dioxide is well known in the art to cause pearlescent effect and [RIEDEL] teaches addition of such pigments in the composition."

Appellants respectfully submit that these assertions misrepresent the facts. The present specification clearly does not teach that each and every composition which comprises mono- and di-fatty esters of glycerol or glycol and sodium and potassium hydroxide is pearlescent. On the contrary, at page 1, last two paragraphs of the present specification it is disclosed that specific emulsions from the prior art such as those described in WO 0110403, WO 9010429, DE 19921186 and DE 19944545 comprise mono- and di-fatty esters of glycerol or glycol in order to ensure pearlescence of the preparation, and that without the addition of these fatty acid esters preparations with pearlescent optics are not accessible or accessible only with difficulty.

Further, in the first paragraph of page 2 of the present specification it is noted that "[i]t was hitherto not possible to formulate pearlescent emulsions which have the

neutralizing agent NaOH and fractions of fatty acids below 12% by weight". At page 2, lines 20-22 of the present specification it further is stated that "[i]t is also disclosed [in The American Perfumer, April 1945, "Manufacturing Vanishing Cream", J.S. Shluka] that pearlescent emulsions can be achieved exclusively by means of high use concentrations of fatty acids. Thus, for example, 16-25% by weight of fatty acids, where 13.3% by weight should be saponified, are used." In comparison, the emulsions of RIEDEL comprise not more than 5% by weight of 14-22 C fatty acids (see, e.g., abstract of RIEDEL). Accordingly, it even is unlikely that any of the compositions according to the teaching of RIEDEL would be pearlescent.

Appellants also point out that the inorganic pigments such as titanium dioxide which are mentioned in col. 11, lines 5-13 of RIEDEL (and relied on by the Examiner) are (optionally) employed in the skin care emulsions of RIEDEL to protect the skin against UV radiation. The Examiner has failed to provide any written (or other) evidence that pigments which are conventionally used in cosmetic compositions for imparting protection against UV radiation (usually) are pearlescent pigments which impart pearlescence to these compositions.

3. Appellants note that the Examiner maintains the position that the recitation of "substantially free" in present claims 119 and 120 encompasses the concentration of 0.2-10 % by weight of fatty acid mono- and/or diglycerides which is to be present in the compositions of RIEDEL. In this regard, the Examiner again relies on a dictionary definition of "substantially" as meaning "being largely but not wholly that which is specified" and asserts that in view thereof, "substantially free does not mean absolutely

free” and therefore, containing 0.2 % of mono- and di-fatty acid esters of glycerol and glycol allegedly is the same as being substantially free of mono- and di-fatty acid esters of glycerol and glycol.

Appellants still are unable to follow this logic and note that the Examiner’s Answer does not address at all Appellants corresponding counterarguments which are set forth in the Appeal Brief and are repeated below for the Examiner’s convenience.

Specifically, Appellants submit again that at least the inventors of RIEDEL apparently did not consider a composition containing 0.2 % of mono- and di-fatty acid esters of glycerol and glycol to be “substantially free” of mono- and di-fatty acid esters of glycerol and glycol. After all, mono- and di-fatty acid esters of glycerol and glycol evidently are an essential component of the compositions of RIEDEL (see, e.g., claim 1 of RIEDEL) and it would defy logic to interpret the teaching of RIEDEL as meaning that the compositions disclosed therein may be “substantially free” of these essential components.

Appellants further point out again that present independent claims 78 and 120 recite, *inter alia*, a lower value of the concentration range of component (III) of 0.01 % by weight, which is a clear indication that even if a composition according to claim 78 or claim 120 comprises a component in a concentration of only 0.01 % by weight the composition it is not considered to be “substantially free” of this component. Accordingly, the present claims themselves leave no doubt that in order to be substantially free of a given substance, a composition would have to contain less than 0.01 % by weight, i.e., much less than the minimum concentration of 0.2 % by weight recited by RIEDEL.

4. At page 13 of the Examiner's Answer it is alleged that "[o]ne of ordinary skill in the art would reasonably be motivated to include urethane polymers along with Stabylen 30 [acrylate/vinyl isodecanoate crosspolymer] into the dermatological composition of [RIEDEL] if the desire was to increase deposition of active ingredients on and in the upper layers of the skin taught by [CHARLTON].... Moreover, the Examiner would like to reiterate the fact that [RIEDEL] clearly taught addition of surfactants, stabilizers and emulsifiers all of which are well-known in the art as stabilizing agents."

In this regard, Appellants respectfully submit that CHARLTON states in col. 3, lines 26-35 (emphasis added):

The skin wash compositions of the present invention may also contain topically acceptable polymers for increasing deposition of the active ingredient on and in the upper layers of the skin. Advantageously such polymers serve to prolong activity of an active ingredient(s) by enhancing skin substantivity, i.e., resistance to wash off. The deposition aiding polymers that are useful herein are urethane polymers including the hydroxy-terminated urethane polymers that are generally described in U.S. Pat. Nos. 4,971,800; 5,051,260 and 5,045,317 all issued to Chess et al.

In other words, according to CHARLTON polyurethanes are used merely for the purpose of imparting resistance to wash-off to the active ingredients (alpha-hydroxy acids) contained in the compositions described therein. This makes sense in view of the fact that these compositions are skin wash compositions which are intended to be rinsed off after use. However, the skin care compositions of RIEDEL (provided in the form of, for example, a skin protection cream, a skin lotion, a cosmetic milk, a sun protection cream, a sun protection milk, a cleansing milk, a sunscreen lotion, a nourishing cream, a day or night cream, etc.) are not supposed to be rinsed off. Accordingly, there is no reason to incorporate a substance which imparts resistance to wash off to any of the

components of the compositions of RIEDEL, let alone for imparting resistance to wash off to any active ingredient thereof.

Appellants further point out that the Examiner has not provided any written (or other) evidence which would be able to support the allegation that surfactants, stabilizers and emulsifiers “are well-known in the art as stabilizing agents”. Appellants also note that “stabilizing agent” is an extremely general term.

5. At page 14 of the Examiner’s Answer it is contended that “Abil Wax 9840 as taught by Evonik Industries Data Sheet is an organopolysiloxane synthesized by linking (i.e. crosslinking) polydimethylsiloxane with long hydrocarbon chains which would necessarily suggest that Abil Wax 9840 is a siloxane elastomer.” Emphasis added. The Examiner further appears to take the position that according to the present specification a “siloxane elastomer” does not necessarily have to be an elastomer.

Appellants point out that they are not aware that “linking” and “crosslinking” are considered to be the same by one of ordinary skill in the art, and neither has the Examiner provided evidence whatsoever for this assertion. Moreover, page 11 of the present specification clearly states that “[s]iloxane elastomers are partially or completely crosslinked and in most cases have a three-dimensional structure.” Accordingly, while a three-dimensional structure is not a prerequisite for a (siloxane) elastomer, an at least partially crosslinked structure is, and this is clearly stated in the present specification.

In view of the foregoing, Appellants are still unable to see any indication in the data sheet for Abil Wax 9840 that this substance is partially or completely crosslinked

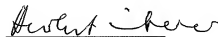
and may thus be considered to qualify as an elastomer. For this reason alone, the Examiner's corresponding arguments are without merit.

CONCLUSION

The request to reverse the rejection of claims 78-136 and to return the application to the Examining Group for prompt allowance is respectfully maintained.

Although no fee is believed to be required for entry of this Reply Brief, the Patent and Trademark Office is hereby authorized to charge any fee that is deemed to be necessary to Deposit Account No. 19-0089.

Respectfully submitted,
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